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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/919,237	07/31/2001	Ivan S. Salgo	10950203-1	2813

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PHILIPS INTELLECTUAL PROPERTY & STANDARDS
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EXAMINER	
NATNITHITHADHA, NAVIN	

ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 04/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/919,237	SALGO ET AL.	
	Examiner	Art Unit	
	Navin Natnithithadha	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 January 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 July 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Claims 1, 2, 5-9, 13, and 15 were amended.

2. Claims 1-15 are pending.

Response to Arguments

3. Applicant's arguments filed 11 January 2005 have been fully considered but they are not persuasive.

In regards to independent claims 1, 4, 7, 8, and 14, the Applicant stated the following on pages 10-11 of the Applicant's Remarks, filed 11 January 2005:

> "With respect to each of claims 1, 4, 7 and 8, Sontag does not teach or suggest generating a trigger signal when a single respiratory signal has a value representing a single place in the respiratory cycle, still less an integrated respiration signal. Applicants' respiratory signal represents the flow of gas into and out of the subject's lungs. Binder includes activity detector 25 for resetting a reset flow indictor for use in the Binder algorithm. It looks to the expiratory flow signal corresponding to completion of expiratory flow. Binder's expiratory flow integrator 23 samples and integrate expiratory flow signal 8 to get a signal proportional to flow volume. Againz Binder does not teach ors uggest a respiratory signal representing the flow of gas into and out of the subject's lungs during the subject's breathlng cycle, nor a trigger generator that includes an integrator for integrating such a respiratory signal to form an integrated respiratory signal, where the integrated respiratory signal is the basis for the point in the complete respiration cycle for triggering.
>
> Hence, even combining Sontag with Binder (assuming arguendo that there is a reason for doing same) would still not render obvious applicants' inventions as claimed.
>
> With respect to claim 14, the Examiner asserts that Sontag teaches a trigger generator for supplying a trigger signal based on a respiratory signal representing gas flow into and out of a subject's lungs, but not an integrator. The Examiner states, however, that it is well known in the art to integrate a flow signal

> from a pneumotachometer to obtain volume signals, such as Binder's integrator 23 (col. 4, l 67 to col. 5, 1. 3), rendering claim 14 obvious.
>
> Applicants respectfully disagree. What the Examiner refers to as flow integrator 23 is actually an expiratory flow integrator, which samples and integrates expiratory flow signal 8 to determine volume of expired gas from the lungs. Accordingly applicants respectfully assert that claim 14 is not obvious in view of Sontag, whether alone or in combination with Binder, for at least the reasons set forth above for the patentability of claims 1, 4, 7 and 8, and request withdrawal of the rejection of claim 14 103(c) based there under 35 USC."

The Examiner respectfully disagrees with this argument. Sontag teaches a system comprising: a monitor ("respiratory signal device") 10 including a sensor 14 for measuring airway flow and lung volume for both inhalation and exhalation ("generating a respiratory signal representing the flow of gas into and out of the subject's lungs during the subject's breathing cycle") (see col. 5, lines 14-27 and lines 34-47); and a computer ("trigger generator") 16 for generating a trigger signal (on or off) 30 or 36 according to the "air flow" values stated in Tables 1-4 (see col. 5, line 53, to col. 6, line 6). In addition, Sontag teaches the computer 16 can generate a trigger signal (on or off) 30 or 36 according to the "lung volume" values stated in Tables 1-4 (see col. 5, line 53, to col. 6, line 6). Sontag does not teach an integrator to integrate a flow signal. However, it is well known in the art to integrate a respiratory flow signal in both the expiratory phase and inspiratory phase to obtain a respiratory volume signal. Binder is an example of such a device. Binder teaches a differential pressure transducer 6 for produce both expiratory and inspiratory flow signals (see col. 4, line 47 to col. 5, line 3, and col. 6, lines 15-35). Expiratory flow integrator 23 and inspiratory flow integrator 45 integrates the expiratory flow and inspiratory flow signals, respectively, and processes these signals to output a continuous respiratory volume signal (see Abstract and col 7,

lines 40-45). It would have been obvious for one of ordinary skill in the art at the time the invention was made to simplify the triggering of a medical device. Therefore, claims 1, 4, 7, 8, and 14 are not novel over the prior art, and thus, the rejection of these claims is MAINTAINED.

Since the subject matter of dependent claims 2, 3, 5, 6, and 9-13 were not traversed, the rejection of these claims are MAINTAINED.

4. Applicant's arguments with respect to claim 15 have been considered but are moot in view of the new ground(s) of rejection.

Claim Objections

5. Claim 1 is objected to because of the following informalities:

Lines 6-11 should be amended to the following to better illustrate the structure of the apparatus (trigger generator):

- - cycle;

an integrator that integrates the respiratory signal to form an integrated respiratory signal; and

wherein the trigger generator generates the trigger signal when the integrated respiratory signal has a value respresenting a selected point in the subject' breathing cycle. - -.

Appropriate correction is required.

Claim 15 is objected to because of the following informalities:

Lines 8-11 should be amended to the following to better illustrate the structure of the apparatus (trigger generator):

- - wherein a trigger generator calculates a differential of the respiratory signal and generates the trigger signal when the differential of the respiratory signal has a value representing a selected point in the subject's breathing cycle. - -.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sontag et al, US 6,076,005 A, in view of Binder, US 4,368,740 A.

In regards to claims 1, 4, 7, and 8, Sontag teaches a trigger generator (computer) 16 and method for supplying a trigger signal to a medical device or data acquisition system 4, comprising: a respiratory signal device (respiratory monitor or differential pressure pneumotachometer) 10 (see col. 5, lines 34-38); and wherein the trigger generator 6 generates a trigger signal (on or off) 30 or 36 when the respiratory signal has a value representing a selected point in the breathing cycle (see col. 5, lines 55-58, and col. 8, lines 22-24). Sontag does not disclose the trigger generator 16 integrates the respiratory signal, i.e. a flow signal. However, it is well known in the art at the time the invention was made to integrate a flow signal from a pneumotachometer to obtain volume signals. For example, Binder teaches using differential pneumotachometer 6 to

measure respiratory flow to generate flow signals and integrating the flow signals to obtain volume signals (see col. 4, line 67 to col. 5, line 3). Additionally, Sontag's device uses volume values to generate trigger signals (see col. 5, lines 57). It would have been obvious for one of ordinary skill in the art at the time the invention was made to simplify the triggering of a medical device. Claims 4, 7, and 8 claims similar subject matter as claim 1 and are rejected as being taught by Sontag in view of Binder for the same reasons above.

As to claims 2, 3, 5, and 6, Binder teaches integrating the respiratory signal (integrator 23) and generating the integrated respiratory signal (integrated flow signal, i.e. volume signal) (see col. 4, line 67 to col. 5, line 3). Sontag teaches generating or receiving the trigger level (maximum and minimum lung volumes) representing a value (threshold) corresponding to a selected point in the subject's breathing cycle (see table 1); and comparing the integrated respiratory signal with a trigger level (see fig. 1); and generating the trigger signal when the integrated respiratory signal corresponds to the trigger value (see fig. 1).

As to claim 9, Sontag teaches the value representing a selected point in the breathing cycle is selected to correspond to a point in the cycle where the motion of the lungs is at a minimum (see col. 4, lines 25-31).

As to claims 10-12, Sontag teaches the medical data system is an ultrasound system, tomographic system, or a MRI system (see col. 5, line 19).

As to claim 13, Sontag teaches a trigger generator (computer) 16 comprising a processor configured to receive a respiratory signal and cause the output of the trigger

signal 30 or 36 (see col. 5, lines 55-58, and col. 8, lines 22-24). Sontag does not teach the respiratory signal device outputs a digital value and integrating the respiratory signal. However, it is well known in the art at the time the invention was made to use digital processing of respiratory signals from a pneumotachometer. For example, Binder teaches a digital computer 116 for processing digital input signals from a differential pressure transducer 6 (see col. 10, line 16). Also, it is well known to integrate a respiratory signal, i.e. a flow signal to obtain volume signals as discussed in claim 1.

In regards to claim 14, Sontag teaches a trigger generator 16 for supplying a trigger signal to a medical device 4 based on a respiratory signal representing the flow of gas into and out of the subject's lungs during the subject's breathing cycle (see col. 5, lines 14-20 and 34-38), the trigger generator comprising: a trigger level source (algorithm) that outputs a trigger level representing the selected point in the subject's breathing cycle (see tables 1, 2, or 3); and a trigger level detector (algorithm) that compares the integrated respiratory signal and the trigger level and generates the trigger signal when the integrated respiratory signal enters into a predetermined relationship with the trigger level (see tables 1, 2, or 3). Sontag does not disclose the trigger generator 16 comprises an integrator that integrates the respiratory signal, i.e. a flow signal, and generates a corresponding integrated respiratory signal. However, it is well known in the art at the time the invention was made to integrate a flow signal from a pneumotachometer to obtain volume signals. For example, Binder teaches using differential pneumotachometer 6 to measure respiratory flow to generate flow signals

and an integrator 23 for integrating the flow signals to obtain volume signals (see col. 4, line 67 to col. 5, line 3). Additionally, Sontag's device uses volume values to generate trigger signals (see col. 5, lines 57).

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claim 15 is rejected under 35 U.S.C. 102(b) as being anticipated by Sontag, US 6,076,005 A, in view of Vogele et al, US 6,318,365 B1.

In regards to claim 15, Sontag teaches a trigger generator (computer) 16 for supplying a trigger signal (on or off) 30 or 36 to a medical device 4, the trigger generator 16 comprising: a respiratory signal device (respiratory monitor) 10 associated with the subject that generates a respiratory signal representing the flow of gas into and out (inspiratory and expiratory phase) of the subject's lungs during the subject's breathing cycle (see col. 5, lines 34-38); and the trigger generator (computer) 16 generates the trigger signal when the respiratory signal has a value representing a selected value in the a respiratory parameter (see Tables 1-3). Sontag does not teach the computer 16 calculates a differential of the respiratory signal. However, Vogele teaches calculating the first derivative of the flow curve with respect to time (see fig. 1(b) and col. 2, lines 29-37). It would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Sontag's computer 16 to compute the derivative of the flow signal in order to obtain "a more distinct transition between the

inhalation and exhalation phases" as suggested by Vogele (see col. 1, lines 20-26). This is desirable for Sontag's system in order to document the full range of organ motion based on the point of full inhalation and full exhalation (see Sontag, col. 6, lines 42-61).

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Navin Natnithithadha whose telephone number is (571) 272-4732. The examiner can normally be reached on Monday-Friday, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone

number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Navin Natnithithadha
Patent Examiner
GAU 3736
15 April 2005